REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on 10/19/2006, and the references cited therewith.

Claim 48 is amended herein. Claims 64-67 are canceled herein without prejudice. Claims 1-47, 51, 58, 61-63, and 69-98 were previously canceled. As a result, claims 48-50, 52-57, 59 and 60 are now pending in this application.

§ 103 Rejections of the Claims

On page 3 of the office action, the examiner rejected claims 48-50, 52-57, 59, 60 and 64-68 under 35 USC 103 as being unpatentable over USP 5997501 ("Gross et al.") in view of USP 6685674 ("Douglas et al."). On page 4 of the office action, the examiner rejected claims 48-50, 52-57, 59, 60 and 64-68 under 35 USC 103 as being unpatentable over Gross et al. in view of USP 5997501 ("Larsen et al."). On page 5 of the office action, the examiner rejected claims 48-50, 52-57, 59, 60 and 64-68 under 35 USC 103 as being unpatentable over Gross et al. alone.

In response, applicant has amended claim 48 to further include the limitations that "the skin penetrating member is contained entirely within the housing when the skin penetrating member is in the retracted position, and the infusion cannula is more flexible than the penetrating member." As amended, claim 48 clarifies that the skin penetrating member must reside entirely inside the housing in the retracted position and further that the infusion cannula is more flexible than the skin penetrating member. The requirement that the infusion cannula be contained within the housing in the retracted position means that the user is not exposed to a hazardous "sharp" after the penetrating member serves its pupose as an insertion device for the infusion cannula. The requirement that the infusion cannula is more flexible than the penetrating member means that the relatively comfortable infusion cannula resides in the user's subcutaneous tissue during use of the fluid delivery device rather than a relatively uncomfortable needle with sufficient rigidity to serve as a penetrating member.

Neither Gross et al., nor Douglas et al. nor Larsen et al., whether considered alone or together, teach or suggest the invention as set forth in amended claim 48.

In particular, Gross et al. teaches a fluid delivery device having a a unitary penetrating member and infusion cannula (e.g., 14, 114, 214, 310), which is described as a "hollow needle" (see, e.g., Gross et al. at col. 11, line 7). The needle must be sufficiently rigid to function as a skin penetrating device when the fluid delivery device is pressed against the skin of the user (see, e.g., Gross et al. at col. 11, lines 6-9). Since the rigid needle also serves as the infusion cannula, the user is left with a rigid (uncomfortable) infusion cannula in his or her subcutaneous tissue for the entire duration of the fluid delivery devices use. Providing a separate penetrating member and infusion cannula with different properties is more than merely rearranging parts or constructing formerly integrated structure in various elements. Nothing in Gross et al. teaches such a structure. Nor does Gross et al. even recognize the problem solved by providing a separate penetrating member and infusion cannula. Thus, neither in re Japiske nor Newin v. Erlichman are applicable to the present case and Gross et al. does not teach or in any way suggest the present invention as set forth in amended claim 48.

As, discussed during the July 24, 2006 telephonic interview, and applicant's previous amendment, Douglas et al. and Larsen et al. are directed to infusion sets and, therefore, do not teach or suggest the inclusion of a dispenser within the housing of the device. Moreover, while both Douglas et al. and Larsen et al. do provide for a separate penetrating needle and infusion cannula, in both references, the penetrating needle (See, e.g., 30 in Fig. 3 of Douglas et al. and 14 in Fig. 18 of Larsen et al.) is a separate element, attached to a hub (See, e.g., 32 in Fig. 3 of Douglas et al. and 3 in Fig. 18 of Larsen et al.), that is inserted through the housing of the main device and then completely withdrawn and discarded. Notably, a variation shown in Larsen et al. shows a rigid infusion cannula that also serves as a penetrating member (Larsen et al. at Fig. 19). Neither Douglas et al, nor Larsen et al. teach or suggest a penetrating member that is contained entirely within the housing in the retracted position.

In view of the foregoing, applicant submits that none of Gross et al., Douglas et al., and Larsen et al., whether considered alone or together, teach or suggest the invention as set forth in amended claim 48. Accordingly applicant submits that the rejections of claim 48 as unpatentable over various combinations of those references are improper and should be withdrawn. In addition, since claims 48-50, 52-57, 59 and 60 depend variously from claim 48, the rejections of those claims are likewise improper and should be withdrawn.

Conclusion

In vew of the foregoing, applicant respectfully submits that the claims are in condition for allowance. The Examiner is invited to telephone Applicant's attorney (781-457-4717) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 503188

Respectfully submitted,

Date April 19, 2007 By /R. Anthony Diehl, Reg. No. 38432/

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